ARTIFICIAL AND TRANSPLANTED ORGANS: MOVABLE PARTS AND THE UNMOVING LAW

*Leslie Pickering Francis**

In the seventeenth century, John Locke asked whether we would end up with the same person if we replaced bodily parts one by one. He concluded that the person would remain the same, despite continued replacement of material parts, because the identity of a human being consists of continued participation in the same organized life.[1]

Locke's speculation is not nearly so hypothetical today as it once must have seemed. We now have available, in more or less developed states, artificial skin, blood vessels, kidneys, ears, joints, hands, feet, hearts and heart valves. We can grasp, pump blood, hear, and filter wastes, all with artificial devices. We can transplant corneas, bone marrow, livers, kidneys, hearts and lungs. With the recent implantation of the artificial heart, there is a growing dispute about whether natural organ transplantation or artificial organ implantation present the best long-range therapeutic prospects.[2] Yet there is very little legal writing, and almost no litigation, specifically directed to the topic of replacement organs, artificial or natural. Perhaps this dearth of legal authority is a welcome reflection of the fact that artificial organs pose no unique or interesting legal questions for us. More likely, it results from the fact that the development of both organ transplantation and artificial organs is a relatively new and burgeoning field, in which legal thinking lags behind technological and medical advances.

There are two analogs to artificial organs with which we have long-standing legal experience: the transfer of natural human organs, tissues and fluids, particularly blood; and the use of medical devices that do not become a relatively permanent part of the patient, e.g., wheelchairs and crutches. Each analog, however, incorporates significantly different interests than the case of artificial organs.

With respect to the effect on the receiving patient, the analogy between implanting artificial organs and transplanting natural organs holds fairly well. Like natural organs obtained from donors, artificial organs replace or supplement the recipient's original body parts. Like

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* Associate Professor of Law and Assistant Professor of Philosophy, University of Utah.

[1] J. LOCKE, AN ESSAY CONCERNING HUMAN UNDERSTANDING, BOOK II, Ch. 27, §§ 3-6 (1975).

[2] *See* Strauss, *The Political History of the Artificial Heart*, 210 N. ENG. J. MED. 332 (1984).

the organ it replaces, an artificial organ becomes a functioning part of the recipient's physical machinery. Artificial organs, however, need not become physically integrated into the recipient in the same manner as his original organs, or in the manner of a natural organ transplant. For example, the wearable artificial kidney and the insulin pump can be detached readily from the patient who uses them, and even the drive system on the artificial heart implanted at the University of Utah in 1982 can be interchanged or replaced. As a result, artificial organs may be more readily accessible than transplanted natural organs; patients waiting in line for these types of devices may have interests that can be satisfied more readily than the interests of patients waiting for a natural organ transplant.

The analogy between artificial organs and transplanted organs breaks down further when we consider their origins. Artificial organs are manufactured, and much of the interest in their development comes from companies that plan to market them for profit. In respect to their origin, therefore, the transfer of artificial organs can be treated as an ordinary commercial transaction. Conversely, there are sound ethical reasons, such as protection against exploitation, for prohibiting living donors of natural organs from selling their body parts. In addition, biological limits on the availability of natural organs have contributed to their persistent, distressing undersupply. It is understandable that much of the present law governing natural organ transplantation focuses on the genuine problem of encouraging organ donation. This focus is myopic, however, for it loses sight of the concomitant need to protect the actual and potential recipients of natural organ transplants. With its emphasis on supply, the law dealing with natural organ transplantation cannot itself be transplanted to deal with the issues and circumstances of commercially manufactured artificial organs.

Medical devices such as crutches or hearing aids are the other analog to artificial organs with which we have legal experience. Here, the analogy holds from the manufacturing side: medical devices are manufactured, usually for profit. But it breaks down from the recipient's side. Prostheses, no matter how important they may be to the patient's quality of life, do not become a new body part of the recipient and may not supply an essential bodily function. Their failure may be a less drastic affair for the patient. Moreover, many medical devices can be reused by a number of patients in succession. The generalizations here are a matter of degree and do not hold in every case; a dialysis machine, for example, does not become a bodily part, but supplies an essential bodily function, and dialysis filters can be re-

used. Nonetheless, because of the role played by artificial organs in sustaining life , the interest in protecting the recipient is likely to be stronger in the case of an artificial organ than in the case of an ordinary prosthesis.

The aim of this article is to anticipate some of the novel legal problems that may be expected to emerge with the growing technology of organ replacement. There is a comprehensive federal statute—the Medical Device Amendments of 1976[3]—designed to minimize risks from the distribution of ineffective, unsafe, or ill-made medical devices. Otherwise, the current legal situation demonstrates a serious failure to think through the problems that will be posed by more widespread use of artificial organs, especially in the areas of tort and contract law. Present legal treatment of natural organ transplantation, moreover, is if anything even more poorly conceived.

I. Federal Regulation of Artificial Organs and Organ Transplantation

Perhaps the only comprehensive legal effort to date in the area of artificial organs and organ transplantation is the federal scheme designed to reduce the risks from medical devices distributed in interstate commerce.[4] This scheme has the potential to protect patients by setting relatively stringent standards, although it remains to be seen how effectively it will work in practice. By contrast, there is no comprehensive federal regulation of the growing field of natural organ transplantation.

A. *Artificial Organs*

Since the passage of the Medical Device Amendments (Amendments) in 1976,[5] producers of artificial organs in interstate commerce have been subject to a complex federal regulatory scheme. The Amendments set out a structure for classifying devices, depending on their importance to human health and the difficulties involved in ensuring their safety. The Secretary of Health and Human Services (HHS) is authorized to promulgate performance standards for devices, where standards are needed and possible, given the current state of research.[6] Where the available technical knowledge does not permit the development of performance standards, but a device is either important to human health or poses a potentially unreasonable

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[3] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified in scattered sections of 21 U.S.C.).
[4] 21 U.S.C. § 331(a) (1982).
[5] Pub. L. No. 94-295, 90 Stat. 539.
[6] 21 U.S.C. § 360c-d (1982).

risk, premarket clearance is required before the device can be introduced into interstate commerce.[7] In addition, the Amendments provide for continued monitoring of marketed devices. The devices may be reclassified, performance standards may be changed, or premarket clearance may be withdrawn.[8] The Secretary may also require public notice of risks, refunds, or recall and repair efforts.[9] Finally, the Amendments allow developers of new devices to seek investigational device exemptions from the standards applied to marketed devices.[10]

The scope of the Medical Device Amendments is extremely broad, ranging from tongue depressors and bedpans to artificial hearts and kidneys. "Device" is defined in the Amendments to include any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" which is intended to affect bodily structure or to be used in the diagnosis, treatment, cure, mitigation, or prevention of disease.[11] Under the Amendments, devices intended for human use are divided into three groups: Classes I, II and III. Class I, the least regulated, includes devices for which safety reasonably can be assured through a series of registration, information access, labelling, and record-keeping requirements.[12] This group also includes devices that do not present an unreasonable risk of illness or injury, provided they are not claimed to be for use in supporting human life or of substantial importance in preventing damage to human health.[13] Examples of devices falling into this first group are containers for storing biological specimens,[14] chambers for cultivating anaerobic microorganisms,[15] straps for holding gas masks in place,[16] tuning forks used to diagnose hearing loss,[17] manual stethoscopes,[18] "crash carts" for storing resuscitation equipment,[19] and the stool on which the anesthesiologist sits during surgery.[20] As these examples illustrate, the devices subject to the limited "general controls" of Class I present very little risk to human health.

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[7] *Id.*
[8] *Id.* § 360c(e).
[9] *Id.* § 360h.
[10] *Id.* § 360j(g).
[11] *Id.* § 321(h).
[12] *Id.* § 360c(a)(1)(A)(i).
[13] *Id.* § 360c(a)(1)(A)(ii).
[14] 21 C.F.R. § 864.3250 (1983).
[15] *Id.* § 866.2120.
[16] *Id.* § 868.5560.
[17] *Id.* § 882.1525.
[18] *Id.* § 870.1875(a).
[19] *Id.* § 868.6175.
[20] *Id.* § 868.6700.

All devices that fall outside of Class I are subject to additional controls under the Amendments. The type of control depends upon whether there is information available about the device sufficient to allow for the development of reasonable performance standards. If performance standards should and can be developed to provide reasonable guarantees of safety and efficacy, a device is to be assigned to Class II.[21] Congress intended safety and efficacy, not mechanical standardization, to be the goals of performance standards.[22] A device is safe if its probable health benefits outweigh probable risks when used as intended with adequate directions.[23] A device is effective when there is reasonable assurance that it will produce clinically significant results in a significant portion of the target population when used as intended with adequate directions.[24]

Performance standards may include design requirements, manufacturing methods, testing procedures, and information to accompany the device.[25] Standards may be developed by the Food and Drug Administration (FDA), by other government agencies, or by the private sector after notice is published inviting offers to develop a standard.[26] Offers to develop standards must include information about the expertise, financial stability, and potential conflicts of interest of the offeror.[27] This system for the development of standards was intended to provide great flexibility while avoiding conflicts of interest where manufacturers serve as their own monitors.[28] Whether it will ultimately succeed in setting rigorous standards will depend upon the degree of care the FDA uses in selecting the available methods for developing standards, and, in particular, upon the selection of offerors from the private sector.

The majority of medical devices have been assigned to Class II. Performance standards have been developed for devices as diverse as kits for testing blood;[29] systems for testing for microorganisms and immune function;[30] anesthesiology equipment;[31] cardiac care devices

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[21] 21 U.S.C. § 360c(a)(1)(B).

[22] S. REP. No. 33, 94th Cong., 1st Sess. 11, *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS 1070, 1081.

[23] 21 C.F.R. § 860.7(d)(1).

[24] *Id.* § 860.7(e)(1).

[25] 21 U.S.C. § 360d(a)(2); 21 C.F.R. § 861.7.

[26] 21 C.F.R. § 861.20(d).

[27] *Id.* § 861.26(a).

[28] S. REP. No. 33, 94th Cong., 1st Sess. 12, *reprinted in* 1976 U.S. CODE CONG. & AD. NEWS 1070, 1081.

[29] 21 C.F.R. §§ 864.5200 - .7925 (1983).

[30] *Id.* §§ 866.2050 - .3930, 866.5040 - .5890.

[31] *Id.* §§ 868.1 - .6885.

such as catheters and electrocardiographs;[32] contraceptive devices such as diaphragms;[33] and a vast range of neurological and neurosurgery devices from skull drills to electrodes.[34]

If Class I controls or Class II performance standards will not adequately guarantee a device's safety and efficacy, and if that device is intended to be used to sustain life or to be of substantial importance in preventing impairment of health, or it presents a potentially unreasonable risk of illness or injury, then the device is placed in Class III.[35] Class III devices require premarket approval before they can be entered into interstate commerce.[36] Many of the more risky and highly publicized devices have been assigned to Class III: IUDs,[37] pacemakers,[38] replacement heart valves,[39] cardiac assist devices,[40] machines for administering electroshock therapy,[41] and high energy cardiac defibrillators.[42] Public concern over injuries associated with pacemakers and IUDs in particular helped motivate Congress to adopt the Medical Device Amendments.[43] Some devices for diagnosing venereal disease[44] and for performing abortions[45] have also been given Class III status. Altogether, as of 1983, some seventy-three devices had been placed in Class III.

Anyone may petition for premarket approval of a Class III device. Petitions must include full reports of investigations concerning the safety and effectiveness of the device, discussions of how the device is made and how it functions, and any samples that may be reasonably requested by the Secretary of Health and Human Services.[46]

If the Secretary finds that the petition does not provide reasonable assurances of the device's safety or effectiveness, under the uses suggested in the petition, premarket approval must be denied.[47] Approval must also be denied for failure to conform to applicable good

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[32] *Id.* §§ 870.1280, 870.2340.

[33] *Id.* § 884.5350. See *Id.* Part 884 for a complete list of the obstetrical and gynecological devices in Class II.

[34] *Id.* Part 882.

[35] 21 U.S.C. § 360c(a)(1)(C) (1982); 21 C.F.R. § 860.3(c)(3) (1983).

[36] 21 U.S.C. § 360c(a)(1)(C).

[37] 21 C.F.R. § 884.5360.

[38] *Id.* §§ 870.3600, 870.3610.

[39] *Id.* § 870.3925.

[40] *Id.* § 870.3600.

[41] *Id.* § 882.5940.

[42] *Id.* § 870.5300(b).

[43] S. REP. No. 33, 94th Cong., 1st Sess. 8, 15 (1975).

[44] *E.g.*, 21 C.F.R. §§ 866.2420, 866.3290, 866.3305.

[45] *E.g., id.* § 884.4270.

[46] 21 U.S.C. § 360e(c)(1).

[47] *Id.* §§ 360e(d)(2)(A),(B).

manufacturing practice regulations, labelling requirements, or relevant performance standards.[48] In this petitioning process, the burden is on the petitioner to make a showing of safety and efficacy, rather than on the Secretary to demonstrate that the device is unsafe or medically useless. The premarket approval process thus is designed to function as a rigorous review process for Class III devices.

Assigning all of the available medical devices[49] to classification categories is a massive undertaking, but critical to the regulatory scheme. The Amendments provide for classification panels to make recommendations to the Secretary.[50] These panels are composed of experts from the relevant scientific and medical disciplines. Each panel must also include a representative from the device industry and a consumer representative as nonvoting members.[51] Panel recommendations are published in the Federal Register, and, after opportunity for comment, the Secretary of HHS promulgates a regulation classifying the device.[52]

The rigor of the scheme is enhanced by presumptions built into the development of the classificatory recommendations. If a device was in commercial distribution before the effective date of the Amendments (1976), and is either intended as an implant[53] or represented to be for sustaining or supporting human life,[54] the classifying panel must recommend Class III designation. An exception is allowed where the Commission finds the designation unnecessary to assure safety and

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[48] *Id.* §§ 360e(d)(2)(C),(D),(E).

[49] The only significant limitation on the Amendment's reach is that performance standards and premarket approval are not required for "custom" devices which are developed by medical order for a particular patient or for the needs of a particular practice, and which are not generally available on the market. 21 U.S.C. § 360j(b).

[50] *Id.* at § 360c(b)(1).

[51] *Id.* § 360c(b)(2).

[52] *Id.* § 360c(d).

[53] A device is an "implant" if it is to be placed in a human body cavity, formed naturally or surgically, and intended to remain there for 30 days or more. 21 C.F.R. § 860.3(d). This definition is intentionally broad; if an implant does not pose serious risks to health, it will not be included in Class III. 43 Fed. Reg. 32994 (1978).

[54] A device is "life supporting or sustaining" if it either is essential to, or yields information essential to, a bodily function important to continued human life. 21 C.F.R. § 860.3(e). Artificial hearts, blood vessels, and implantable kidneys are "implants" and are also "life supporting" if they perform essential bodily functions. Artificial ears and eyes are "implants." Artificial limbs, hands or feet are "implants" if they are attached into a bodily cavity. Present day dialysis machines or cardiac monitors are "life supporting or sustaining." Artificial skin is "life supporting" if it is essential to keeping the patient alive, as in the case of a burn victim. Nearly all artificial organs, therefore, will fall into Class III unless findings are made that their safety and efficacy can be guaranteed by alternative categorization. As a result, artificial organs will almost certainly be subject either to premarket clearance or to the performance standard requirements of the Amendments.

efficacy. Any such decision must be accompanied by a statement of reasons from the panel.[55] Likewise, a decision by the Secretary not to place an implant or life support device in Class III must be accompanied by "a full statement of reasons," with supporting documentation and a statement of risks to health, if any, that the device presents.[56] Devices developed after 1976 are placed initially in Class III, unless they are affirmatively assigned to Class I or Class II by the Secretary.[57] Implants or life support devices cannot be assigned to Class I or Class II without the findings required for implants which were on the market in 1976.[58]

The regulatory scheme set out in the Amendments neither ends nor begins with a device's marketplace debut. Based on new information about a device, the Secretary has the statutory authority to change a device's classification or to revoke any performance standard or premarket clearance regulation in effect with respect to that device. The Secretary may seek a recommendation from the panel that classified the device, but any recommendation so secured must be published in the Federal Register.[59] Classifications may be altered through a petition process governed by FDA regulations. These regulations provide that petitions for reclassification must be accompanied by a supplemental data sheet, a full statement of reasons why the device should be reclassified and why the reclassification will assure safety and efficacy. Also required is information known to the petitioner that might counsel against the reclassification request.[60] Because a petitioner for reclassification has a relatively onerous task it may prove difficult to get a device reclassified into a more lenient category.

In addition to the authority to reclassify, the Secretary may take more drastic steps to protect the public from defective or otherwise harmful devices. To avoid an unreasonable risk of substantial harm to human health, the Secretary may order publication of notice to all those involved in the use of the device: manufacturers, health professionals, and users.[61] Notice must be sent to device users unless the Secretary finds that the notice itself would be a greater risk to health

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[55] 21 U.S.C. § 360c(c)(2)(C). Transitional provisions governing devices formerly classified by the FDA as drugs are to the same effect. *Id.* § 360j(l)(1).

[56] *Id.* § 360c(d)(2)(B).

[57] *Id.* § 360c(f)(1).

[58] *Id.* §§ 360c(f)(2)(B)(i), (C)(i).

[59] *Id.* § 360c(e).

[60] 21 C.F.R. § 860.123(a).

[61] 21 U.S.C. § 360h(a).

than its absence. If this is so, the notice to health professionals must require them to inform their patients of the risks involved and of any ameliorative steps that might be taken.[62] If, after opportunity for an informal hearing, the Secretary finds that notice alone would not protect the public from an unreasonable risk of substantial harm, those responsible for the device may be ordered to come up with a plan for repair, replacement, or refund.[63] Remedies under this section of the statute explicitly do not preclude additional recovery under state or federal law.[64] Given the uncertainties of state law,[65] however, these other remedies may prove evanescent.

To allow for the development of new devices, the Amendments permit the Secretary to exempt devices under experimentation from much of the regulatory scheme, including performance standards and premarket clearance requirements.[66] Investigators must acquire an "investigational device exemption" (IDE) in order to begin interstate shipment of a device designed for experimental use.[67] Unless a device poses "significant risks," an IDE is obtained automatically if a sponsor follows appropriate labelling and record-keeping practices and conforms with federal requirements governing review of research with human subjects, unless the FDA informs the sponsor otherwise.[68] A device poses "significant risks" if it presents a potential for serious risk to health, safety, or welfare.[69] Redundantly, the federal regulations also specify that a device poses "significant risks" if it presents that potential for serious risk *and* is intended as an implant; is purported to be for use in supporting or sustaining human life; or is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or preventing impairment of health.[70] Thus, research on all artificial organs must undergo review as research on human subjects, and generally will require formal application[71] to the FDA

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[62] *Id.*

[63] *Id.* § 360h(b).

[64] *Id.* § 360h(d).

[65] *See infra* text accompanying notes 91 to 181.

[66] *Id.* § 360j(g).

[67] 21 C.F.R. § 812.1(a).

[68] *Id.* § 812.2(b).

[69] *Id.* § 812.3(m)(4).

[70] *Id.* §§ 812.3(m)(1)-(3).

[71] Formal application for an IDE is a comprehensive process. It requires submission of a complete report about earlier investigations of the device, with copies of all published and unpublished adverse information. *Id.* § 812.20(b)(2), 812.27(b)(1). It also must include a protocol demonstrating the scientific soundness of the proposed experiment, and an analysis of the risks posed to subjects from the research. *Id.* §§ 812.25(b), (c). Certification of review as research with human subjects is also required. *Id.* § 812.25(h).

for an IDE as well.

The federal scheme for review of research with human subjects relies on a system of Institutional Review Boards (IRBs) at institutions sponsoring the research. Regulations have been promulgated by the FDA governing research within its purview, and by HHS, governing research under its more general sponsorship.[72] These regulations now have been synchronized on all but a few provisions. IRB review[73] must assess the risks and benefits of proposed research and assure that human subjects give informed consent before participating. IRBs are required to disapprove research in which risks to subjects are not minimized or are not reasonable in relation to anticipated direct benefits, either for the subjects or in terms of the knowledge gained from the research.[74] IRBs must also disapprove research if the selection of research subjects is inequitable or if informed consent is not obtained from subjects.[75] Special provisions have been included in the HHS regulations for assessing the risks and benefits of obtaining informed consent when research includes children or prisoners as subjects.[76] At this point, no special regulations have been adopted governing research on mentally disabled subjects.

B. *Federal Regulation of Natural Organ Transplantation*

In contrast to the regulation of medical devices, there is no comprehensive federal regulation of organ transplantation. If it is research and involves the testing of investigational drugs or devices, organ transplantation is subject to the federal regulations governing research with human subjects. For example, organ transplantation programs in which cyclosporine was tested came under IRB review. Organ transplantation research that is federally funded must receive

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The FDA may reject an IDE application if it contains false or misleading information, or if the risks of investigation are greater than the benefits to subjects or of the knowledge to be obtained. It may reject an application if the informed consent of subjects is not adequately assured. *Id.* § 812.30(b). The FDA also has the authority to withdraw approval of an IDE. *Id.* § 812.30(c).

[72] 21 C.F.R. §§ 56.101 - 56.124; 45 C.F.R. §§ 46.101 - 46.409.

[73] For general discussion of IRB review, see Bosso, *Considerations of the Institutional Review Board in Artificial Organ Development*, 11 JOURNAL OF CONTEMPORARY LAW 61 (1984).

[74] 21 C.F.R. §§ 56.111(a)(1),(2); 45 C.F.R. §§ 46.111(a)(1),(2).

[75] 21 C.F.R. §§ 56.111(a)(3),(4); 45 C.F.R. §§ 46.111(a)(3),(4) (1983). For consent to be "informed," the subject must have an adequate opportunity to consider participating in the research in an unpressured situation; must be given an explanation of the research in understandable language, including a description of what will be done, risks, benefits, and alternatives; must not be made to waive any rights or relieve the researcher from liability for negligence; and must be entitled to leave the experiment at any time without loss of benefits that would otherwise be available. 21 C.F.R. § 50.25(a); 45 C.F.R. § 46.116(a).

[76] 45 C.F.R. §§ 46.401 - 46.409, 46.301 - 46.306.

IRB approval.[77] Other federal standards have been promulgated for the supply of blood and blood components. Other than these few federal restrictions, the regulation of organ transplantation or the transfer of natural body tissues or fluids is entirely a state matter.

Without a nexus to federal concerns, there is no mandate for organ transplantation research to be subject to IRB review. Some states, however, require review of all research conducted on human subjects.[78] Individual institutions sponsoring research may also require IRB review of research that falls outside the federal purview. The University of Utah, for example, requires all research with human subjects under its sponsorship to receive IRB clearance.[79] It appears that a number of the major organ transplant programs across the country regularly subject their protocols to IRB review, at least until a research procedure becomes established therapy.[80]

As described above, IRB review includes a determination that the benefits of research outweigh its risks. Subject selection must also be equitable, and subjects must not be allowed to participate without voluntary and informed consent.[81] Once transplant programs have passed beyond research, they are no longer subject to these special federal protections. Patients must rely on the background of state law to ensure they are adequately protected from unsafe, unwanted, or unfair medical procedures.

The FDA regulations controlling blood and blood products classify these fluids as pharmaceuticals and subject them to the labelling requirements of the Food and Drug Act.[82] Good manufacturing practice requirements specify personnel qualifications, equipment, record-keeping, and operating procedures for blood suppliers.[83] These include the requirement that donors be screened for suitability.[84] Additional standards for specific blood products stipulate that donors of whole blood must be examined briefly for good health,[85] and that plasma donors must receive initial examinations from a physician.[86] Plasma source donors are also protected by a requirement of in-

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[77] 21 C.F.R. § 50.1(a); 45 C.F.R. § 46.101.

[78] *E.g.*, 44 NEW YORK PUB. HEALTH LAW §§ 2440-46 (McKinney 1977).

[79] UNIVERSITY OF UTAH, INSTITUTIONAL REVIEW BOARD (MEDICAL), POLICIES AND PROCEDURES, I.

[80] Conversations with members of IRBs, on file with the author.

[81] *See supra* notes 72 - 75 and accompanying text.

[82] *See* 21 C.F.R. § 201.

[83] *Id.* §§ 606.20 - .170.

[84] *Id.* § 606.100(b)(1).

[85] *Id.* § 640.3.

[86] *Id.* § 640.63(b).

formed consent.[87]

There has been a recent flutter of Congressional activity concerning natural organ transplants. Concern, however, has been directed entirely towards ensuring an adequate supply of organs and financing expensive transplant procedures. In the fall of 1983, several bills were introduced into Congress to facilitate the availability of donated organs by establishing, inter alia, a national organ registry.[88] These bills, however, ignore issues of patient protection, except that they prohibit the purchase of natural body parts.[89] Of course, it is in the interest of desperately ill patients to have donated organs available, but it would be better still not to forget safety in the rush to generate a supply.

In summary, in the case of natural organ transplants, federal protections for research subjects may be available, at least until a transplantation technique ceases to be experimental. In the case of artificial organs, the federal regulatory scheme provides a filter which, if it works properly, will keep ill-designed, poorly made, or ineffective devices from reaching patients. At the experimental stage, it will protect patients as research subjects by ensuring that patient selection is equitable and accompanied by informed consent. In neither case, however, does the federal scheme provide any recovery for the patient who is injured by a defective device or organ, given poor medical treatment, or denied treatment because of an inequitable patient selection process or the inability to pay. Patients must rely upon state law to fill these gaps; but, at present, state law does not do so very well.

II. Organ Replacement Under State Law

Standard doctrines of medical tort law—liability for negligence or battery in the case of physical contact without consent—quite clearly apply to organ replacement, just as they apply to other cases of medical treatment. Less clear, however, is the relevance of other doctrines of tort and contract law. Both implants and transplants involve what is arguably a product: the organ. The doctrines of strict product liability in tort or implied warranty of merchantability in contract, therefore, might apply in either case, especially if the organ transfer is a for-profit transaction. A number of states, however, have interposed statutes designed to encourage natural organ donation by insu-

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[87] *Id.* § 640.61.

[88] H.R. 4320, 98th Cong., 1st Sess. (1983); S. 2048, 98th Cong., 1st Sess. (1983); H.R. 4180, 98th Cong., 1st Sess. (1983).

[89] H.R. 4320 § 352A(a).

lating donors and health care personnel from liability beyond traditional battery or negligence. If the expensive process of organ replacement is not financed publicly, other commercial law doctrines, such as taking a security interest in the implanted organ, might be involved. The expense of organ replacement may also place new strains on the rights and duties of the physician-patient contractual relationship as they are traditionally defined. Potential areas of strain include the physician's right not to enter the relationship, the patient's supposedly absolute right to withdraw, and the rights and duties of a health care provider when a patient fails to pay. The result of all this is a set of very clouded legal protections for the recipients of natural organs, potentially major differences between the legal rights and remedies of recipients of donated organs and those of artificial organs, and an unsatisfactory understanding of the physician-patient relationship in either case.

A. *Traditional Tort Law: Karp v. Cooley*

The only litigated case involving the implantation of an artificial organ illustrates how traditional battery and malpractice theories might apply to artificial organs.[90] In 1969—well before adoption of the federal scheme regulating medical devices or research with human subjects—Dr. Denton Cooley, a Houston heart surgeon, implanted an artificial heart in Haskell Karp. After an unsuccessful effort to remove scar tissue from Karp's heart, and after it became clear that the heart was too damaged to permit recovery from surgery, Dr. Cooley implanted the artificial device. It was intended as a temporary measure only, to allow time for a heart transplant to be arranged. Karp remained alive on the artificial heart for 64 hours, including periods of time in which he was awake and responsive. A transplant was then performed, but Karp died of pneumonia and renal failure 32 hours later. His widow brought suit, alleging that her husband had not consented to the artificial heart implantation and that Dr. Cooley had been negligent in attempting to remove the scar tissue from her husband's heart. The court held that she had failed to prove a case on either theory.[91]

In traditional tort law, absent extenuating circumstances such as the emergency nature of the treatment, it is a battery for a physician to operate upon a patient without consent.[92] Today, the physician's

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[90] Karp v. Cooley, 493 F.2d 408 (5th Cir. 1974) *cert. denied*, 419 U.S. 845 (1974).

[91] *Id.* at 421-23.

[92] *E.g.*, A. HOLDER, MEDICAL MALPRACTICE LAW 225-30 (2d ed. 1978).

failure to disclose the risks of treatment is more likely to be tried as malpractice if it falls short of the standard of care required of physicians in a jurisdiction and results in harm to the patient.[93] In some jurisdictions, the standard of care required for disclosure of risks is physician-centered; it requires proof of customary practices of disclosure in an area,[94] or of what the reasonable physician, practicing a similar type of medicine in a similar locality, would disclose.[95] Other jurisdictions argue that the basis of informed consent is the patient's right to decide what will happen to his body. These jurisdictions have adopted a patient-centered standard of disclosure: the physician is required to reveal what the reasonable person in the patient's situation would want to know.[96]

Texas law, applied by the court in *Karp*, adheres to the reasonable physician standard, and requires expert medical testimony about the disclosures that would be made by the reasonable practitioner in the relevant medical community.[97] In this case, Mrs. Karp introduced evidence that Mr. Karp was neither informed of the uniquely experimental nature of the proposed artificial heart nor of the risks that might result from its use. She did not, however, provide proof of "*what* risks under these circumstances a physician should disclose."[98] Perhaps she could not produce the required proof; under the experimental circumstances of her husband's case, there was no recognized standard of what the reasonable physician would disclose.

If so, the case illustrates how a physician-centered standard of disclosure may break down at the vanguard of medical practice. In jurisdictions where the reasonable physician standard is applied, when standards of disclosure have yet to be established—as may well be the situation for artificial organ technologies under development—patients will be unable to prove that a failure to disclose was malpractice. In a jurisdiction in which the standard of disclosure is based on what the reasonable patient would want to know, by con-

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[93] *Id.* at 231.

[94] *E.g.*, Riedisser v. Nelson, 111 Ariz. 542, 534 P.2d 1052, 1054-55 (1975); Fuller v. Starnes, 597 S.W.2d 88, 90 (Ark. 1980).

[95] *E.g.*, Ziegert v. South Chicago Community Hosp., 99 Ill. App. 3d 83, 425 N.E. 2d 450, 458-59 (1981); Hood v. Phillips, 554 S.W.2d 160, 166 (Tx. 1977).

[96] *E.g.*, Canterbury v. Spence, 464 F.2d 772, 783 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); Scott v. Bradford, 606 P.2d 554, 558 (Okla. 1979); Wilkinson v. Vesey, 295 A.2d 676, 688 (R.I. 1972); Keogan v. Holy Family Hosp., 95 Wash. 2d 306, 622 P.2d 1246, 1254 (1980); Trogun v. Fruchtman, 58 Wis. 2d 596, 207 N.W.2d 297, 314 (1973). *See generally* Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533 (1970) (arguing for reasonable patient standard of disclosure).

[97] *Karp*, 493 F.2d at 420.

[98] *Id.* at 421 (emphasis in original).

trast, a basis for recovery would be provable even in the most experimental medical case. Similar inability to prove a case is likely where disclosure standards have not coalesced for emerging techniques of organ transplantation. In jurisdictions in which liability for natural organ transplantation is confined to intentional wrongdoing or negligence,[99] the use of a physician-centered standard of disclosure may prove especially curtailing to patient remedies.

Mrs. Karp also alleged that Dr. Cooley had been negligent in attempting surgical repair of Mr. Karp's heart. Here again, she was required to prove that Dr. Cooley's conduct had fallen short of the standard of care provided by similarly situated medical specialists, and her proof failed.[100] The court held that under Texas law this evidentiary standard would not be affected by the fact that treatment afforded her husband was experimental.[101]

Mrs. Karp's failure to prove negligence in the initial effort to repair her husband's heart may not have been related to the case's experimental aspects, which developed after the surgery failed. Nonetheless, it is clear here, too, that it is difficult to prove a malpractice theory when standards of treatment have not yet developed. In a malpractice case, the plaintiff must prove that the practitioner's care fell below that provided by other physicians—or specialists, if a specialty is in question—in similar communities, or, increasingly, in the region or nation.[102] If there are no recognized procedures for an experimental case, plaintiffs will be unable to recover on a malpractice theory.

B. *Strict Products Liability*

The doctrine of strict products liability is another theory on which patients might recover for damages caused by malfunctioning artificial organs. Initially, this doctrine seems more likely to yield remedies for patients than a negligence action, because it requires proof

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[99] *See infra* notes 146 to 150 and accompanying text.

[100] 493 F.2d at 423.

[101] *Id.* at 423-24.

[102] *E.g.*, Priest v. Lindig, 583 P.2d 173, 175-78 (Alaska 1978) (same or similar locality); White v. Edison, 361 So. 2d 1292, 1295 (La. Ct. App. 1978) (national standard for specialists); Shilkret v. Annapolis Emergency Hosp. Ass'n, 276 Md. 187, 349 A.2d 245, 253 (Md. 1975) (national standard for all physicians); Halligan v. Cotton, 193 Neb. 331, 227 N.W. 2d 10, 12 (1975) (same or similar locality); Orcutt v. Miller, 595 P.2d 1191, 1194-95 (Nev. 1979) (national standard for board-certified specialist). Jenkins v. Parrish, 627 P.2d 533, 537 (Utah 1981) (similar locality rule requires application of national standards to board-certified specialist in major city). *See generally* A. HOLDER, *supra* note 92, at 58-59; 1 D.W. LOUISELL & H. WILLIAMS, MEDICAL MALPRACTICE ¶ 8.06 (1983 & Supp. Nov. 1983).

that the product was defective rather than that the defendant was negligent. As it has been applied to transfers of natural bodily parts and prostheses, however, the doctrine has not been very helpful to plaintiffs. One difficulty is that the transfers at issue have been held to be "services" and not "sales."[103] Another lies in the standards that have been adopted for deciding when a risky product is defective.

As formulated in the Restatement (Second) of Torts, the doctrine of strict liability requires the plaintiff to show that: (1) the defendant was engaged in the business of selling products of the kind at issue, (2) the product was not altered after it left the control of the defendant, (3) the product was defective in the sense that it was unreasonably dangerous, and (4) the product caused the plaintiff harm.[104] The Restatement explains that "unreasonably dangerous" means "dangerous to an extent beyond that which would be contemplated by the ordinary consumer."[105] Some products cannot be made entirely safe. Drugs, for example, often cause untoward side effects, even more so in experimental situations in which their full potential is unknown. When a product is unavoidably unsafe, the Restatement suggests that the test for whether it is "unreasonably dangerous" should be whether the benefits of the product outweigh its risks.[106]

The Restatement approach to an unavoidably risky product, however, is not entirely congruent with its initial explanation that a product is unreasonably dangerous when it has danger beyond ordinary consumer expectations. Risks, even though undetectable and ultimately justifiable, may be entirely unanticipated by the ordinary user of a product. The line of cases considering whether a strict liability remedy should be available for damages caused by transfusions of hepatitis- infected blood is illustrative of the incongruity. The vast majority of courts have held against recovery in those cases. Some courts have pointed out that no reliable test exists for detecting hepatitis and have concluded that blood is therefore unavoidably unsafe.[107] Other courts, applying a risk/benefit analysis, have contended that the social utility of having blood available, hepatitis test or not, far outweighs the risk that a few patients will become ill.[108] Analo-

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[103] *See infra* notes 138-46 and accompanying text.

[104] RESTATEMENT (SECOND) OF TORTS § 402A (1965).

[105] *Id.*, Comment i.

[106] *Id.*, Comment k.

[107] *E.g.*, McMichael v. American Red Cross, 532 S.W.2d 7 (Ky. Ct. App. 1975); Moore v. Underwood Memorial Hosp., 147 N.J. Super. 252, 371 A.2d 105 (1977).

[108] *E.g.*, Fisher v. Sibley Memorial Hosp., 403 A.2d 1130, 1134 (D.C. App. 1979); Brody v. Overlook Hosp., 127 N.J. Super. 331, 317 A.2d 392, 397 (1974); Hines v. St. Joseph's Hosp., 86 N.M. 763, 527 P.2d 1075, 1076-77 (1974).

gous reasoning has been applied by courts in the few cases litigating the issue of whether a medical device such as a pacemaker is unreasonably dangerous.[109]

The ordinary patient, however, may not expect to get hepatitis as a result of the blood transfusion, despite the fact that the risk is very real. Indeed, this is the conclusion reached by the few courts that have allowed recovery on behalf of patients contracting hepatitis from infected blood.[110] Those courts have relied upon the ordinary user standard and concluded that hepatitis-infected blood is unreasonably dangerous.

If the reasoning of the blood transfusion cases were applied to replacement organs, liability would be precluded in most jurisdictions. Both natural organ transplants and artificial organ implants cause harm ineluctably: natural organs may be rejected and artificial organs may fail. On the risk/benefit approach to strict liability, recovery for unavoidable damage from a replacement organ would be possible only when benefits of the organ replacement procedure at issue do not outweigh the risks. If the benefits of the artificial heart outweigh the risks of failure, for example, the risk/benefit approach would preclude recovery for damage caused by the sort of unpredictable valve breakage that necessitated additional surgery for the first recipient of the Utah artificial heart.[111] The impact of the ordinary user standard, by contrast, would depend upon whether user expectations had coalesced and what they were. If, for example, recipients of prosthetic hip joints expected to have to replace them relatively frequently, a joint that failed quickly would not be unreasonably dangerous—even it if were possible to design a more long-lasting prosthetic device.

The approaches of the blood transfusion cases are less than satisfactory. First, to conclude from the inability to discover a defect that a product is unavoidably unsafe is to insulate producers of highly dangerous products from liability, so long as the defects cannot be discovered. To add the requirement that the benefits of a product must outweigh its risks, however, is not to add enough. Having the product and doing without it are two extremes bounding a wide range of strategies for reducing a product's risks. For example, a more accurate blood test is not the only possible method for reducing the risks of hepatitis from blood. Donated blood is less likely than

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[109] *E.g.*, Dreiling v. General Elec. Co., 511 F.2d 768, 776 (5th Cir. 1975).

[110] *E.g.*, DeBattista v. Argonaut-Southwest Ins. Co., 403 So. 2d 26, 31 (La. 1981); Cunningham v. MacNeal Memorial Hosp., 47 Ill. 2d 443, 266 N.E.2d 897 (Ill. 1970).

[111] DeVries, *et al.*, *Clinical Use of the Total Artificial Heart*, 310 N. ENG. J. MED. 274 (Feb. 2, 1984).

purchased blood to be infected; several states now either prohibit blood banking for profit or require bought blood to be used only when volunteer blood is unobtainable.[112] A proper risk/benefit analysis, therefore, should consider whether the cost/benefit ratio of the product as presently designed is more favorable than the comparable ratio for available alternative designs.

This kind of cost/benefit analysis engages the court in difficult questions of social policy. But it carries out more fully the Restatement's suggested program for deciding whether a product is unreasonably dangerous by weighing the risks and benefits of the product in its current form against available alternatives. Moreover, it subjects products that are likely to cause harm to a more exacting scrutiny and encourages efforts to design them as safely as possible. This scrutiny seems especially important for products such as replacement organs that can cause great damage to life or health.[113]

While certainly an improvement, this amended cost/benefit approach still ignores a central policy of strict products liability: compensating the consumer for damage when he has had no choice about avoiding the risk of harm. Including consumer expectations in a determination of when a product is unreasonably dangerous appears to realize this goal more fully. If a consumer has no idea that a product has potential risks, he will not be in a position to try to avoid them. Thus it seems reasonable to allow recovery when a product is more dangerous than normally expected, despite the possibility that on balance the product is designed to minimize risks.[114]

It does not follow from this discussion, however, that if a product meets consumer expectations, it is not unreasonably dangerous. Consumers may simply be resigned to expect too little from the products they use. This concern led California to adopt a far more satisfactory two-tier approach to defining a product defect. The test analyzes first, whether the product has risks outside the expectations of the ordinary consumer, and second, whether the advantages and risks of the product as designed outweigh the advantages and risks of alter-

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[112] Wisconsin prohibits commercial blood banking. WIS. STAT. ANN. § 146.31 (West 1974). Florida and California both require blood to be labelled as "paid" or "volunteer" and specify that paid blood cannot be used unless volunteer blood is unavailable. FLA. STAT. ANN. § 381.601 (West Supp. 14A 1983); CAL. HEALTH AND SAFETY CODE §2 1603.5 (Deering 1982). Illinois allows transfusion of paid blood only with a physician's order and a note on the patient's chart explaining the order. ILL. ANN. STAT. ch. 111 ½, § 602-6 (Smith-Hurd Supp. 1983-84)

[113] *E.g.*, 3 L.R. FRUMER & M.I. FRIEDMAN, PRODUCTS LIABILITY § 34A[1] (1983).

[114] Utah's Product Liability Act adopts this standard by statute. UTAH CODE ANN. § 78-15-6(2) (1977).

native designs.[115] The California test not only takes consumer expectations into account but also seems likely to provide manufacturers with independent incentives to design products to minimize risks.[116] The California approach is obviously not in line with the majority of the blood transfusion cases. If the predominant analyses of those cases are applied to organ replacement, injured patients will in all likelihood not be compensated even though reasonable improvements in the replacement organ were possible, and even though risks far exceeded expectations.

Another doctrine of strict liability — that a product may be defective because of the manufacturer's failure to warn consumers of its risks — will not fill the gaps that remain in protection. The doctrine may be applied in such a way that a manufacturer need not warn a patient and that patient may never know of any risks associated with the product he was using, and yet no liability would attach to the manufacturer. It is commonly held that manufacturers of risky drugs and medical devices have a duty to warn users. Both breast prostheses and IUDs, for example, have been held to require warnings on this ground.[117] The policy argument for requiring the warnings is to allow the consumer a choice, if possible, about whether and how to use the product. In the case of prescription drugs and devices, however, courts have held that warnings need only be given to physicians, unless the FDA specifically requires warnings to patients as well.[118] Unless physicians can be relied upon to act as "learned intermediar[ies]" in communicating warnings to patients,[119] this limitation undermines the policy behind the duty to warn of a product's risks.

C. *Breach of Warranty*

Another potential theory of recovery for a patient injured by a replacement organ is breach of warranty under the Uniform Commercial Code. Many states have statutes precluding suit on a breach of warranty theory for defects in transplanted human body parts.[120]

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[115] New Jersey has also adopted the California approach. *See* Suter v. San Angelo Foundry & Mach. Co., 81 N.J. 150, 406 A.2d 140, 150-51 (1979); Special Project, *Recent Developments in Commercial Law*, 11 RUT. CAM. L.J. 527, 589-613 (1980).

[116] Schwartz, *Foreword: Understanding Products Liability*, 67 CALIF. L. REV. 435, 461-62 (1979).

[117] *E.g.*, Perfetti v. McGhan Medical, 99 N.J. 645, 662 P.2d 646 (1983); McKee v. Moore, 648 P.2d 21 (Okla. 1982).

[118] Terhune v. A.H. Robins Co., 90 Wash. 2d 9, 577 P.2d 975, 978 (Wash. 1978) (en banc).

[119] *Id.*

[120] *See infra* notes 140-43 and accompanying text.

Even ignoring this limitation, however, there are many respects in which current breach of warranty theory is not well equipped to handle the problems posed by artificial organs.

The Code enumerates three warranty theories of relevance here: express warranties, implied warranties of merchantability, and implied warranties of fitness for particular purposes. Express warranties are affirmative representations by the seller that a product has the characteristics claimed.[121] Implied warranties of merchantability arise from the sale itself: a merchant seller is charged with representing that the goods he conveys are of average quality and fit for ordinary purposes, unless he specifies otherwise.[122] An implied warranty of fitness for a particular purpose arises when the seller has reason to know the buyer's particular needs and the buyer relies on the seller's selection of goods.[123] In most medical situations, any implied warranty of fitness is likely to collapse into an implied warranty of merchantability. For a medical device to be fit for the patient's purposes, simply is for it to be of fair average quality of its kind.[124] The difference between the two theories may be important, however, in a state which specifically excludes any implied warranty of merchantability for human body parts.

A first significant barrier to recovery by patients on a breach of warranty theory is the requirement of privity of contract. Although the Code is drafted to enable states to adopt alternatives to privity,[125] more than half the states have continued to insist on some type of privity in a breach of warranty action.[126] Patients who receive new organs from physicians or health care facilities are unlikely to be in privity with the original manufacturers or procurers of the organs. In states insisting on privity, they will not be able to win on a breach of warranty theory.

A second major difficulty in a suit for breach of warranty on a defective replacement organ involves the largely uncharted Code territory of whether a warranty has been made or disclaimed. Under the Code, express warranties can be avoided by silence—they simply are not made—and implied warranties can be expressly disclaimed.[127]

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[121] U.C.C. § 2-313(1) (1978).

[122] *Id.* § 2-314.

[123] *Id.* § 2-315.

[124] *E.g.*, Friedman v. Medtronic, Inc., 42 A.D. 2d 185, 345 N.Y.S.2d 637 (1973) (pacemaker). Where medical devices are custom designed, however, there may be a separate implied warranty of fitness.

[125] U.C.C. § 2-318.

[126] U.C.C. § 2-318, 1A U.L.A. 55 (1976).

[127] U.C.C. § 2-316(2).

Remedies for breach of warranty also can be limited, for example, to the repair or replacement of defective parts—little help to the person whose pacemaker electrode has failed although excluding damages for personal injury from consumer goods is presumptively unconscionable.[128]

The federal regulations governing commercially marketed medical devices probably compel the manufacturer to make at least some express warranties. Medical devices used in commerce must, with certain exceptions, be labelled; and labelling must include a statement of intended uses and adequate directions for use.[129] The FDA regulations, however, do not require that the label represent the device as safe or effective for intended uses. There remains a question of interpretation whether a given label expressly warrants that a medical device will perform as expected.[130] FDA also does not prohibit warranty disclaimers, but under the Magnuson-Moss Act a supplier who makes any written warranties with respect to a consumer good cannot disclaim implied warranties.[131] It thus appears that producers of medical devices, including artificial organs, cannot disclaim implied warranties of merchantability or fitness for particular purpose.

Transferors of natural body parts other than blood, however, are not covered by the federal labelling requirements. Absent state law to the contrary, they could avoid making express warranties and disclaim any implied warranties. A few states have labelling requirements for some natural body parts, including blood, but many do not.[132] There is also some very limited authority to the effect that if it is unconscionable to exclude remedies for personal injuries from a breach of warranty, it is also unconscionable to disclaim all implied warranties.[133] Otherwise, under state law it seems quite possible that transactions involving bodily parts could entirely disclaim implied warranties.

A final uncertainty in using breach of warranty for defective re-

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[128] *Id.* § 719(3).

[129] 21 C.F.R. § 801 (1983).

[130] Indeed, federal regulations for labelling of investigational devices specify that their labelling must bear the caution that the device is investigational and avoid any representation that it is safe or effective. *Id.* § 812.5.

[131] 15 U.S.C. § 2305 (1982).

[132] *E.g.*, CAL. HEALTH & SAFETY CODE § 1603.5 (Deering 1982); FLA. STAT. ANN. § 381.601 (West Supp. 1983).

[133] *See* 3 U.C.C. SERVICE (MB) § 7.03(2)(1980); Schwartz, *supra* note 116, at 456-57; Note, *Legal Control on Warranty Liability Limitation Under the Uniform Commercial Code*, 63 VA. L. REV. 791 (1977). Alabama has adopted an altered version of § 2-316 which codifies this inference. ALA. CODE § 7-2-316(5) (1980).

placement organs is the interpretation to be given an implied warranty of merchantability. The Code explains that merchantable goods must, among their other characteristics, be "fit for ordinary purposes for which such goods are used."[134] If this provision were given a strong literal meaning—that any failure of a good used as ordinarily intended is a breach of the implied warranty of merchantability—then any case of failure of a properly implanted organ in a properly managed patient who follows medical directions would involve a breach of the warranty. This approach, however, would make the manufacturer a complete insurer of his product, even more so than under strict liability. The prevailing view seems to be that the standards for deciding whether a product is unreasonably dangerous under section 402A of the Restatement, and whether it is fit for ordinary purposes under section 314 of the Code, should be the same. If goods are not fit for ordinary purposes, they are unreasonably dangerous and vice versa.[135] Perhaps the only theoretically cogent explanation of the relationship between the two standards is that to interpret unreasonable dangerousness in terms of the expectations of ordinary consumers for strict liability purposes reflects the warranty roots of strict liability.[136] Without further articulation of a distinction between the two doctrines, implied warranty cannot be used to solve the substantive inadequacies of strict products liability discussed above.

D. *Blood Transfusions and Organ Transplants: State Limitations on Liability.*

States have chosen a wide variety of ways to limit the liability of donors, suppliers and providers of health care for damage from the transfer of natural body parts. These limitations on liability are motivated by the hope of encouraging supplies, although many have been in effect for twenty years and the undersupply of organs continues. Some state statutory limits rule out patient remedies except for the traditional intentional torts and negligence; the reach of other statutes is either more limited or less clearly defined. In the interests of protecting patients, these limits should not be applied by analogy to the development of artificial organs, which appears to be a fully commercial enterprise. If they are not so applied, however, the law will give strikingly different remedies to patients receiving defective arti-

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[134] U.C.C. § 2-314(2)(c).

[135] *See, e.g., Perfetti*, 662 P.2d at 654; *McMichael*, 532 S.W. 2d 7.

[136] *E.g.*, Barker v. Lull Engineering Co., 143 Cal. Rptr. 225, 573 P.2d 443, 456 (1978); Schwartz, *supra* note 116, at 448, 458.

ficial and donated organs. This result will occur despite the fact that the two may be alternative therapies and each was obtained in a sale for profit.

The Uniform Anatomical Gift Act,[137] now adopted in all states, was designed to further organ donation at death. The Act creates two immunities from liability. A donee is not to be liable for refusing a gift or in good faith failing to carry out the wishes of a donor.[138] Anyone who causes tissues to be removed in good faith reliance on a gift is not liable for the removal.[139] Both of these immunities are critical to donor and physician participation in anatomical giving, and the Uniform Act makes no further efforts to allocate liability among donors, health care personnel, transfer agencies or donees.

Most states, however, have adopted additional statutes which limit the application of strict products liability and implied warranty to the transfer of human bodily parts. Many of these statutes sweep quite broadly, extending blanket immunity to both commercial and non-commercial enterprises.

A number of states specify that the transfer of human body parts, whether for profit or not, is to be considered a "service" and not a "sale."[140] Some apply this doctrine to blood only.[141] These state statutes are intended to preclude suit on strict liability or warranty theories, and sometimes say so explicitly.[142] Even without explicit statement, these statutes succeed in blocking implied warranty suits, for implied warranties arise under the Uniform Commercial Code only

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[137] 8A U.L.A. 15 (1983).

[138] *Id.* at § 7(c).

[139] *Id.*

[140] ALA. CODE § 7-2-314 (1980); COLO. REV. STAT. § 13-22-104(2) (1974); CONN. GEN. STAT. § 19a-280 (1983); IND. CODE. ANN. § 16-8-7-2 (Burns 1983); IOWA CODE ANN. § 142A.8 (West Supp. 1983); KY. REV. STAT. ANN. § 139.125 (Baldwin 1983); ME. REV. STAT. ANN. tit. 11 § 2-108 (Supp. 1983-84); MICH. STAT. ANN. § 14.15(9121) (Callaghan 1980); MINN. STAT. ANN. § 525.928 (West 1975); MO. ANN. STAT. § 431.069 (Vernon Supp. 1984); NEB. REV. STAT. § 71-4001 (1981); OHIO REV. CODE. ANN. § 2108.111 (Page 1976) (excludes hair); W. VA. CODE § 16-23-1 (1979); WIS. STAT. ANN. § 146.31(2) (West Supp. 1983). Wisconsin also precludes the sale of blood for profit, *id.* § 146.31(1) (1974).

[141] CAL. HEALTH & SAFETY CODE § 1606 (Deering 1982); KAN. STAT. ANN. § 65-3701 (1980) (also precludes warranties for blood); MISS. CODE ANN. § 41-41-1 (1981); UTAH CODE ANN. § 26-31-1 (Supp. 1983).

[142] There are many variations on this theme. Colorado and Wisconsin rule out any suits for damage, absent negligence, in the case of such services. Connecticut and West Virginia preclude suit on an implied warranty theory; Indiana and Michigan specify that there are to be no implied warranty or strict tort liability suits for services with respect to human body parts. Iowa grants immunity for strict liability suits, but stipulates that any provider of the services in question warrants due care and conformity to accepted, current medical standards. Missouri precludes suit on an implied warranty theory for defects that cannot be detected or removed. *See supra* note 140.

for sales or analogous transactions.[143] The effect of these provisions on strict liability, however, is somewhat less clear. If courts apply the doctrine of strict liability to the sale of services, and there is some movement in this direction,[144] these statutes leave the door theoretically open to a strict liability suit. It is unlikely that the door would be open to suits against medical professionals—suits which would, at least in the case of organ transfers, involve a radical shift in the basis of malpractice liability from negligence to strict liability.[145] It is also unlikely that the door would be open to suits against non-profit agencies such as hospitals and blood banks, because their fundamental goal is amelioration of the patient's health.[146] These rationales collapse, however, when the defendant is a commercial entity engaged in the business of supplying replacement bodily parts.[147]

Some states have applied the "service not sale" doctrine in a more limited fashion.[148] Perhaps most consistent with the underlying rationale for strict liability is Idaho's view that the transfer of blood is a service except when rendered by a paid blood donor or a profit-making blood bank.[149] Other states attempt to protect suppliers of natural bodily parts from liability by specifically limiting the theories on which suit can be brought.[150] Another group of states precludes

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[143] U.C.C. § 2-102.

[144] *See, e.g.*, Greenfield, *Consumer Protection in Service Transactions—Implied Warranties and Strict Liability in Tort*, 1974 UTAH L. REV. 661.

[145] *E.g.*, Hoven v. Kelble, 79 Wis. 444, 256 N.W.2d 379 (1977); Note, *Comparative Approaches to Liability for Medical Maloccurrences*, 84 YALE L.J. 1141 (1975).

[146] *E.g.*, McDonald v. Sacramento Medical Found. Blood Bank, 63 Cal. App. 3d 866, 133 Cal. Rptr. 444 (1976); St. Luke's Hosp. v. Schmaltz, 188 Colo. 353, 534 P.2d 781 (1975).

[147] *E.g.*, Belle Bonfils Memorial Blood Bank v. Hansen, Colo. 569 P.2d 1158 (Colo. 1978) (en banc). This case involved a transfusion that antedated the Colorado "service not sale" statute. The court noted cryptically that the "statute attempts to preclude the use of any non-fault theory of recovery in any blood transfusion case against any defendant," without commenting on the success of the attempt. *Id.* at 1185 n.1.

[148] North Carolina declares that its "service not sale" statute does not "alter or restrict the liability of a person or institution in negligence or tort in consequence of these services," N.C. GEN. STAT. § 130A-410 (Supp. 1983), thus arguably contemplating the possibility of a strict liability suit. Illinois specifies that anyone providing the service of transferring a part of the human body warrants professional standards of care and conformity with Illinois' blood labelling act, limiting the use of purchased blood. ILL. ANN. STAT. ch. 111 ½ §§ 620-6, 5102, 5103 (Smith Third Supp. 1983). Montana limits the "service not sale" doctrine to blood obtained by hospitals, care facilities, or physicians from sources in which they have no financial or controlling interest. It also insulates physicians, care facilities, and blood banks from liability without fault. MONT. CODE ANN. §§ 50-33-102 to -104 (1983). Nevada applies the doctrine only to the transmission of hepatitis in blood. NEV. REV. STAT. § 460.010 (1979). Washington applies the doctrine only to hepatitis contracted from volunteer blood. WASH. REV. CODE ANN. § 70.54.110 (1975).

[149] IDAHO CODE § 39-3702 (1977).

[150] Six states offer blanket immunity from liability, absent negligence or willful misconduct,

suit on an implied warranty theory by specifying that transactions in blood or other parts of the human body are not covered by Article 2 of the Uniform Commercial Code.[151] Others state more generally that no implied warranties apply to the transfer of blood or tissues.[152] Like the "service not sale" statutes, these provisions leave the possibility of a strict liability suit theoretically open.[153]

Only New Jersey, New York, and Rhode Island have made no statutory efforts to extend immunity to those who are engaged in the transfer of human body parts. New York, however, has a long line of cases holding that such transfers, even by profitmaking facilities, are services rather than sales.[154] New Jersey, while suggesting disapproval of the service/sale distinction, has found blood to be an unavoidably unsafe product for purposes of strict liability.[155]

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to all transferors of human bodily parts. ARK. STAT. ANN. § 82-1608 (1976); HAWAII REV. STAT. § 327-51 (1976); N. D. CENT. CODE § 43-17-40 (1978); PA. STAT. ANN. tit. 42, § 8333(a) (Purdon 1982); TEX. STAT. ANN. art. 4590-3(2) (Vernon 1976); WYO. STAT. § 35-5-110 (1977). Texas couples this immunity with a prohibition on blood sales in which payment is made within fifteen days. This prohibition is intended as a disincentive to the riskiest group of blood donors and violation results in loss of the immunity. TEX. STAT. ANN. art. 4590-3(3)(a), (b) (Vernon 1976). New Hampshire extends blanket immunity to transferors of blood only. N. H. REV. STAT. ANN. § 507:8-b (1983).

[151] ALASKA STAT. § 45.02.316(e)(1980); DEL. CODE ANN. tit. 6, § 2-316(5) (1974); FLA. STAT. ANN. § 672.316(5) (West Supp. 1984); MASS. ANN. LAWS, ch. 106, § 2-316(5) (Michie/Law. Co-op. 1976); N.D. CENT. CODE § 41-02-33-3.d (1983); S.D. CODIFIED LAWS ANN. § 57A-2-315.1 (1980).

[152] OKLA. STAT. ANN. tit. 63 § 2151 (West 1973); OR. REV. STAT. § 97.300 (1983); S.C. CODE ANN. § 44-43-10 (Law. Co-op. 1976); TENN. CODE ANN. § 47-2-316(5) (1979); VA. CODE § 32.1-297 (1979).

[153] A Louisiana court, arguing that strict liability represents a broader reallocation of risks than implied warranty, concluded that its legislature could have taken the broader step but had not. DeBattista v. Argonaut Southwest Ins. Co., 403 So. 2d 26 (La. 1981). *But see* McDaniel v. Baptist Mem. Hosp., 469 F.2d 230 (6th Cir. 1972) (Tennessee statute abolishing implied warranties for human bodily parts under U.C.C. precludes strict liability suit); Rostocki v. Southwest Fla. Blood Bank, 276 So.2d 475 (Fla. 1973) (same holding under Florida law). The Louisiana legislature subsequently amended the Louisiana Code to abolish strict liability suits for defects in transferred body parts against physicians, hospitals and nonprofit blood banks, but not against other profit-making facilities. LA. REV. STAT. ANN. § 9:2797 (West Supp. 3A 1984). Arizona similarly extends its immunity from strict liability and implied warranty suits to physicians, hospitals, and nonprofit blood or tissue banks. ARIZ. REV. STAT. ANN. § 32-148 (1976).

New Mexico and Maryland extend the most limited statutory immunity. In New Mexico, there are no implied warranties in the transfer of human blood, and strict liability does not apply to the transmission of hepatitis in blood. N.M. STAT. ANN. § 24-10-5 (1978). By implication, strict liability suits might be possible in New Mexico for defects in blood other than hepatitis. In Maryland, there are no strict liability or implied warranty suits for the transfer of hepatitis in blood, but no other liability is precluded. MD. HEALTH-GEN. CODE ANN. § 18-402 (1982).

[154] *E.g.*, Samuels v. Health & Hosp. Corp. of New York, 432 F. Supp. 1283 (S.D.N.Y. 1977); Perlmutter v. Beth David Hosp., 308 N.Y. 100, 123 N.E.2d 792 (1954).

[155] Brody v. Overlook Hosp., 128 N.J. Super. 331, 317 A.2d 392 (1974).

Statutes extending immunity from suits to transferors of parts of the human body are thus common. They range from blanket preclusion of suits on all but the classic tort theories of negligence and battery, to very narrow preclusion of strict liability for the transfer of hepatitis in blood. However, arguments that have moved courts and legislatures to protect physicians, blood banks, and hospitals—genuine providers of service—should not apply to commercial transfers of artificial organs. As both the use of artificial organs and natural organ transplants become more widespread, significant differences in the remedies available to patients injured by the different strategies of treatment may emerge. If artificial organs become a more realistic alternative to natural transplants, and the supply situation eases, legislatures should have new reason to question the wisdom of the rush to extend immunity beyond genuine services to profitmaking facilities engaged in the transfer of parts of the human body.

E. *Financing Arrangements for Artificial Organs*

Liability for defects is by no means the only area of commercial law in which artificial organs are likely to pose novel challenges. Financing arrangements are another. Artificial organs are likely to be very expensive. In 1980, the costs for dialysis were $1.1 billion and they are estimated to reach $2.8 billion by 1981.[156] It is estimated that the artificial heart will cost at least $10,000[157] and $20,000 is the price Kolff Medical has charged for prototypes of the artificial heart and driver implanted in Utah.[158] Kolff Medical estimates that its artificial ear will cost between six and twelve thousand dollars.[159] If the costs of artificial organs are not shared through public financing or insurance programs, methods must be developed to improve access for patients who cannot pay the full price. Since artificial organs are in some cases reusable, these arrangements might include security interests in the device to finance purchases, leases, and user fees for machines that can be shared.

Nothing in the Uniform Commercial Code would prohibit arranging financing with artificial organs as collateral.[160] If such arrange-

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[156] U.S. HEALTH CARE FINANCING ADMINISTRATION, 1981 END-STAGE RENAL DISEASE ANNUAL REPORT TO CONGRESS 38, 107.

[157] U.S. OFFICE OF TECHNOLOGY ASSESSMENT, THE ARTIFICIAL HEART: COST, RISKS AND BENEFITS (1982).

[158] Carter, *The Business Behind Barney Clark's Heart,* MONEY, April, 1983, at 130, 133.

[159] *Id.*

[160] An artificial organ is a consumer good, *see* U.C.C. §§ 9-105(1)(h), 9-109(1), and an interest

ments emerge, however, so will the inevitable question of what can be done when the purchaser can no longer pay. The Code prohibits self-help repossession that involves a breach of the peace.[161] Removal of an attached organ necessarily would qualify, but removal of an unattached device such as equipment for hemodialysis at home would not. There is some authority that precludes money judgment executions on the debtor's essential basics,[162] and indeed in most cases the artificial organ would be a basic. In addition, the Bankruptcy Code exempts professionally prescribed health aids from the bankrupting estate.[163] But these beginnings by no means form a complete system for dealing with the contingency where a patient becomes unable to pay for his artificial organ. They do not, for example, touch the issues of whether lenders should be able to select only the better credit risks for artificial organs, or whether sellers would be obligated to continue servicing a debtor that does not pay.

F. *Consequences for the Physician-Patient Relationship*

The traditional model of the physician-patient relationship is based on freedom of contract. Physicians or patients may refuse to enter the relation for whatever reason. Patients may terminate the relationship at will. Once the relation has begun, physicians are obligated to continue treatment but may withdraw with adequate notice. The expense and experimental nature of artificial organs may place new strains on these entrenched features of the relationship.

First, it is a textbook proposition that physicians may turn down patients for any reason: too many other patients, concern about the patient's ability to pay, or even sheer dislike or prejudice.[164] Absent contractual obligations, such as emergency room "on call" arrangements,[165] the law does not obligate physicians to provide care even to acutely ill patients.

Physicians also may set limits from the outset on treatment relationships. Care may be limited by specialty.[166] It may be limited to a single visit[167] or to consultation or assistance.[168] It may be limited

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taken to secure a loan for its purchase would be a purchase money security interest in consumer goods, *see id.*, § 9-107.

[161] *Id.* § 9-503.

[162] *See* N.Y. CIV. PRAC. LAW § 5205(a) (McKinney 1978).

[163] 11 U.S.C. § 522(d)(9) (1982).

[164] A. HOLDER, *supra* note 97, at 7.

[165] Hiser v. Randolph, 126 Ariz. 608, 617 P.2d 774 (Ct. App. 1980).

[166] *E.g.*, Skodje v. Hardy, 47 Wash. 2d 557, 288 P.2d 471 (1955).

[167] *E.g.*, Miller v. Blackburn, 170 Ky. 263, 185 S.W. 864 (1916).

[168] *E.g.*, Shannon v. Ramsey, 288 Mass. 543, 193 N.E. 235 (Mass. 1934).

geographically.[169] It may be limited to particular locations for medical reasons.[170] Or the care may be limited to specific places or times for the convenience of the physician;[171] house calls are not obligatory. Some of these limits can be justified by the demands of good medical care, but others clearly cannot.

Hospitals may have somewhat less freedom. Those receiving Hill-Burton Act construction funds are required to make a reasonable volume of services available to people without means.[172] Some state regulations require private general hospitals to provide emergency care, regardless of the patient's ability to pay.[173] Other states require private hospitals with emergency rooms to treat all patients in acute need of care on the theory that having emergency facilities is a representation to the public that emergency care will be available.[174] This obligation, however, does not extend to admitting the emergency patient.[175] Nor are hospital emergency rooms obligated to provide non-emergency care.[176]

Thus, on the traditional model there is no obligation to treat any particular patient in need of an organ replacement. Physicians, hospitals, and suppliers of replacement organs are not required to accept patients who seem poor financial risks, patients without families, patients they dislike, or any other type of patient. Selection of patients in need of organ replacement might become seriously inequitable on this model.

There is one background constraint. Those engaged in state action are subject to the fourteenth amendment guarantees of equal protection and due process, and recipients of Medicare funds must not discriminate on racial or ethnic grounds in violation of Title VI of the Civil Rights Act, or on grounds of handicap or age.[177] Thus, the worst

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[169] *E.g.*, McNamara v. Emmons, 36 Cal. App. 2d 199, 97 P.2d 503 (Dist. Ct. App. 1939).

[170] For example, an obstetrician may insist upon hospital birth. *E.g.*, Vidrine v. Mayes, 127 So. 2d 809 (La. Ct. App. 1961).

[171] *E.g.*, Urrutia v. Patino, 297 S.W. 512 (Tex. Civ. App. 1927).

[172] 42 U.S.C. § 291 c(e) (1976). The statute allows for an exemption if the requirement is not financially feasible.

[173] *E.g.*, Guerrero v. Copper Queen Hosp., 112 Ariz. 104, 537 P.2d 1329 (1975) (en banc).

[174] *E.g.*, Wilmington Gen. Hosp. v. Manlove, 54 Del. 15, 174 A.2d 135 (1961); Hunt v. Palm Springs Gen. Hosp., 352 So. 2d 582 (Fla. Dist. Ct. App. 1977); Richard v. Adair Hosp. Found., 566 S.W.2d 791 (Ky. Ct. App. 1978); Stanturf v. Sipes, 447 S.W.2d 558 (Mo. 1969); *see also* RESTATEMENT (SECOND) OF TORTS § 323 (1965). For a criticism of this theory, see Note, *Emergency Care: Physicians Should be Placed Under an Affirmative Duty to Render Essential Medical Care in Emergency Circumstances*, 7 U.C.D. L. REV. 246 (1974).

[175] *E.g.*, Harper v. Baptist Medical Center-Princeton, 341 So. 2d 133 (Ala. 1976); Joyner v. Alton Ochsner Medical Found., 230 So. 2d 913 (La. Ct. App. 1970).

[176] *E.g.*, Fabian v. Matzko, 236 Pa. Super. 267, 344 A.2d 569 (1975).

[177] 42 U.S.C. § 2000d-1; 45 C.F.R. §§ 80, 84.4(a), 90.12 (1983).

inequities of discrimination based on race, ethnic origin, or sex are precluded. But other inequities, such as the exclusion of patients without money or family support, are not. The problem will in all likelihood be worsened if relatively few centers have the capacity to perform highly sophisticated forms of organ replacement, and alternatives to an arbitrary selection process are not readily available. Concerns about the fairness of the patient selection process in the early stages of hemodialysis[178] become mooted by the decision to underwrite the program under Medicare. These concerns will recur if lifesaving organ replacement becomes available therapy but is not publicly funded, and they will require rethinking of the traditional assumption that the decision to accept a patient for treatment is entirely discretionary.

A second entrenched feature of the physician-patient relationship that may need to be reconsidered is the assumption that the patient can terminate the relationship at will. If an organ replacement is scarce or expensive therapy, and one patient has been treated while others wait, arguably the lucky patient incurs moral obligations to participate in whatever cooperative systems have made his good fortune possible. For example, long-term monitoring of patients with replacement organs may be important to the development of better therapeutic techniques. Perhaps beneficiaries of organ replacement should continue to be monitored, and are not morally free simply to walk away from an organ replacement program. Moreover, depending upon how the replacement organ functions, it may not be possible for the recipient to cease to be part of a treatment program and continue to survive. If an artificial organ requires servicing, for example, ending participation in a program may raise all the issues posed by decisions to decline lifesaving treatment.

Finally, the more widespread use of organ replacements as therapy may force reconsideration of the physician's right to withdraw from the treatment relationship. The traditional view of the physician-patient relationship is that absent initial understandings to the contrary, the duty to continue treatment extends until treatment is no longer necessary, the patient discharges the physician, the relationship is dissolved by mutual consent, or the physician withdraws from the relationship.[179] The patient's inability or outright refusal to pay

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[178] *E.g.*, Comment, *Patient Selection for Artificial and Transplanted Organs*, 82 HARV. L. REV. 1322 (1969).

[179] See A. HOLDER, *supra* note 92, at 372; D.W. LOUISELL & H. WILLIAMS, *supra* note 102, at ¶ 8.02.

will not justify the physician from summarily refusing further care.[180] A physician who violates these duties may be sued for abandonment.[181]

The duty to continue treatment, however, does not permanently lock physicians into treatment relationships. They may withdraw and thereby terminate the obligation to treat. Withdrawal may be effected for almost any reason, including the patient's failure to pay, but it requires adequate notice and the opportunity for the patient to seek alternative care.[182] With a patient who does not pay, therefore, the physician who wishes to end the relationship without liability should tell the patient to make arrangements for alternative care, preferably help with such arrangements, and continue to treat the patient for a reasonable time in the interim.

Organ replacement potentially poses the hardest case for this traditional recommendation: the patient for whom no alternatives can be found. In such a case is the physician obligated to continue treatment, even if the patient has no prospects of paying? There appear to be no reported cases that present exactly this dilemma. All the reported cases in which physicians have been held liable for abandonment of patients who cannot pay involve summary refusals to treat patients who, with time, might have found other care, probably at public expense.[183] One commentator has maintained that the duty to treat would persist when the patient cannot find alternatives, but provides no argument or authority for the claim.[184]

Nonetheless, it seems doubtful that the freedom of contract model would require the physician to continue treatment in such cases. On this view, the physician in beginning treatment binds him or herself not to terminate it arbitrarily, but does not undertake to provide unlimited care, whatever the costs. It is terrible to contemplate withdrawing treatment from a patient who has no alternatives. But the freedom of contract view crystallizes an underlying dilemma that will become increasingly pressing as organ replacement becomes more widely available. The costs of continued therapy for those who cannot pay either can be absorbed by physicians, shared in some other

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[180] *E.g.*, Ricks v. Budge, 91 Utah 307, 64 P.2d 208 (1937).

[181] *See* Comment, *The Action of Abandonment in Medical Malpractice Litigation*, 36 TUL. L. REV. 834 (1962).

[182] *E.g.*, Capps v. Valk, 189 Kan. 287, 369 P.2d 238 (1962); Johnson v. Vaughn, 370 S.W.2d 591 (Ky. 1963); A. HOLDER, *supra* note 92, at 372.

[183] *E.g.*, Gray v. Davidson, 15 Wash. 2d 257, 130 P.2d 341 (1942), *aff'd on other grounds*, 136 P.2d 187 (1943) (en banc); *Ricks*, 64 P.2d 208.

[184] A. HOLDER, *supra* note 92, at 373.

way, or not incurred at all. If at some point it becomes unfair to impose the costs on physicians and too burdensome to share them, life-saving therapy will have to end for some patients. Arguably this is the only rational choice, but it must be made fairly and not simply on the basis of individual physicians' decisions about when to withdraw.

III. Conclusion

Organ replacement is a medical triumph. But it seems all too likely to become a legal and social debacle. As replacement moves from experimentation to therapeutic potential, the pressures of widespread demand may make rational policy choice increasingly difficult. Organ replacement will save lives, but it will do so more fairly if we move now to reexamine the tort and contract law obligations of those involved in the replacement process.